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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,013	12/24/2001	Rosann Kaylor	KCX-461 (15790)	1072

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,013

Applicant(s)

KAYLOR ET AL.

Examiner

Lyle A. Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-75, 1-26 and 1-39 of copending Application No. 10/013973, 10/026,415 and 10/084,763 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because all teach systems having a membrane for sample acquisition and a reading device to analyze the sample for the analyte(s) of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 42,45-48,50-51 and 56-61 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Anderson et al. (USP 6,867,051).

Anderson et al. teach a lateral flow test device. Column 2 lines 36+ teach stand reference curves may be incorporate into a bar code on the test device which has been read on the claimed "first stop position for a reference reading". Column 8 lines 10+ each a slot to receive the test device in a reading device which has been read on the claimed "reading device". The taught reading device contains all of the claimed light barrier structures as evidenced by the same function being accomplished by both. Column 10 lines 42+ teach a L.E.D. in the reading device that has been read on the claimed "L.E.D.".

Claims 42,45-48,50-51 and 56-61 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Allen et al. (USP 5,837,456).

Allen et al. teach in column 8 an instrument used with a single use test device for making transmittance, reflectance, etc., measurements. The instrument may have a L.E.D. light source, optics, a detector and means to control, store and display data. Column 11 line 22 teaches the test device can be a lateral flow test device. Column 8 lines 54+ teach a reference electrode that initiates the measurement sequence that has been read on the claimed "first stop position".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 43-44, 49 and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. or Allen et al. in view of Phillips et al.

See Anderson and Allen supra.

Anderson and Allen are silent to the claimed spring loaded pressure plate, notches in the test strip to ensure proper insertion into the reading device and the relative sizes/shapes of the reading area.

Phillips et al. teach a method and apparatus for determination of an analyte in a small volume blood sample. Test strip(10) comprises a handle(12), a circular sample addition aperture(14), a positioning notch(15) and a reagent pad(11). The strip is placed in meter(60) that comprises LED(5) to illuminate the sample, detector(6) to record the change, means to correlate and display the results(8,19-22). Pressure plates pressing down on both sides of strip to hold it in place as seen in figure 3 and a cover(90) that is a light barrier. Meter(60) meets the claimed requirements of being capable of placing the strip in more than one position, such a first position where the strip is in the meter and a second position where the notch(15) is mated with post(65). Further, the port that receives strip(10) has light absorbing member on the base around the area where the strip is placed to prevent light from escaping. Column 6 lines 29+ teach the size of the reagent pad(11) as having an area of 10-100 mm² and a diameter of 2-10mm. Column 11 lines 10+ teach the aperture(14) has a diameter of 2-10mm which meet the claimed relationships between the aperture and area of the detection zone.

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The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable has well known and expected results. The spring loaded pressure plate, notches in the test strip to ensure proper insertion into the reading device, the relative sizes/shapes of the reading area all have well know and expected results and would be result effective variables.

It would have been within the skill of the art to modify Anderson et al. or Allen et al. in view of Phillips et al. and use a spring loaded pressure plate, notches in the test strip to ensure proper insertion into the reading device and the claimed relative sizes/shapes of the reading area.as optimization of result effective variables.

Response to Arguments

Applicant's arguments with respect to claims 42-61 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743


